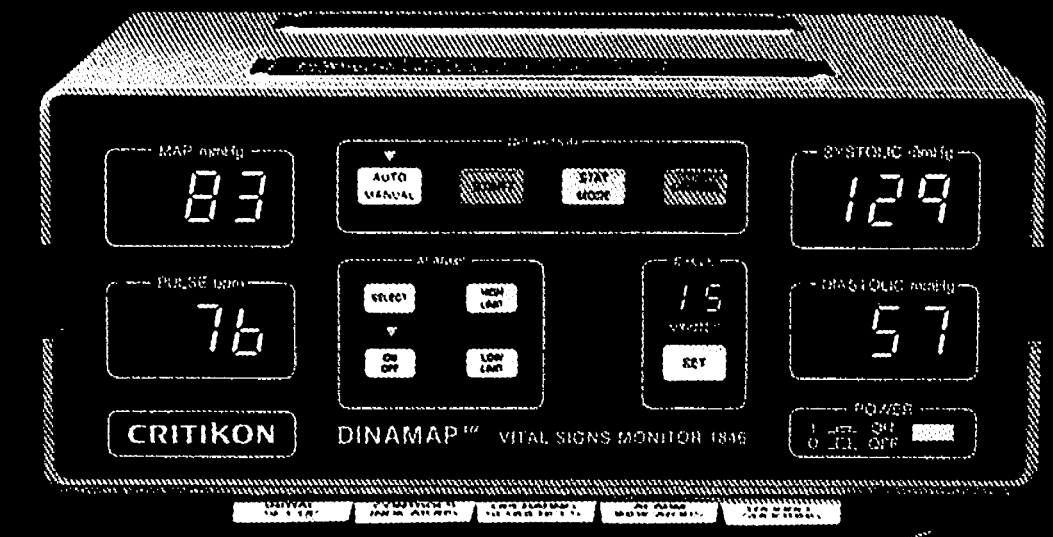

DINAMAP™ Adult/Pediatric and Neonatal
Vital Signs Monitor, Model 1846

WARRANTY

CRITIKON, INC. ("Critikon") warrants to the purchaser that the DINAMAP™ Vital Signs Monitor, exclusive of expendable parts and other accessories, shall be free from defects in material and workmanship for a period of one year from the date of purchase. Critikon's sole obligation with respect to any such defect is limited to the repair with new or remanufactured parts or, at Critikon's option, replacement of the monitor.

This warranty is made on the condition that prompt notification of a defect is given to Critikon within the warranty period. Critikon shall have the sole right to determine whether a defect exists.

This warranty extends to the original purchaser only. This warranty does not apply to monitors that have been altered, subjected to misuse, negligence, unauthorized repair, or accident, or operated other than in accordance with the instructions.

This warranty represents the exclusive obligation of Critikon and the exclusive remedy of the purchaser regarding defects in a monitor. THIS WARRANTY IS GIVEN IN LIEU OF ANY EXPRESSED OR IMPLIED WARRANTIES, INCLUDING THE WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WHICH WARRANTIES ARE DISCLAIMED. NO PERSON IS AUTHORIZED TO MODIFY, IN ANY MANNER, CRITIKON'S OBLIGATION AS DESCRIBED ABOVE.

Critikon shall not, in any case, be liable for special, incidental or consequential damages arising from breach of warranty, breach of contract, negligence or any other legal theory.

Section 1. Introduction

1.1 General

The DINAMAP™ Vital Signs Monitor was designed to non-invasively and automatically measure systolic and diastolic pressure, mean arterial pressure (MAP), and pulse rate for Neonatal or Adult/Pediatric patients. Results are displayed on large, easy-to-read digital displays. Adaptive internal programs reject most artifacts and automatically compensate for a wide range of patient variables.

The DINAMAP™ Monitor is effective and versatile. It continues to monitor during most clinical crises when other indirect measurement methods may fail. It can be used in any hospital area where critical care is administered, for example, emergency room, operating room, recovery room, intensive care unit, cardiac care unit, renal dialysis unit, burn unit, etc.

1.2 Manual Scope and Effectivity

This Operation Manual was prepared for the operator of the DINAMAP™ Vital Signs Monitor. It contains instructions for use, device applications, limitations, and routine performance verification procedures. To achieve satisfactory results, the operator must read this manual thoroughly before attempting to use the monitor.

Changes to this manual, either in response to user inputs or to continuing product improvements will be accomplished through reprinting. Changes occurring between printings will be addressed through Change Information Sheets and replacement pages. If a Change Information Sheet does not accompany this manual, it is correct as printed.

If, in the normal use of this manual, errors, omissions, or incorrect data are noted, please complete the Publications Change Request Form included in the back of this manual. Submit the form to:

Marketing Services
Critikon, Inc.
4110 George Road
Tampa, Florida 33614

1.3 Related Publications

INSTRUCTION CARDS: Just below the front panel, the operator will find five tabbed instruction cards. These cards are permanently attached to the unit and will slide out for easy access. The cards include information and instructions on INITIAL SETUP, CONTROLS and INDICATORS, OPERATING SEQUENCES, ALARM INDICATORS, and TROUBLESHOOTING malfunctions.

SERVICE MANUAL: A service manual containing service and repair parts information is available. Information contained in the service manual is directed to qualified service personnel. If a service manual was not included with your monitor, a Service Manual Request Card is provided in this manual. To obtain a copy of the service manual, fill out the card and mail it to Critikon, Inc. Be sure to include the serial number of your monitor(s).

Set with off to on
Cal Mode 1
Set sec. time
Cal Mode 2
Set 3rd time
Cal Mode 3
Volt.
MAP 5V
Pulse 3.7V Batt for Clock
Sys. +12V
Dia -12V

(Sys Wind 10 I
Set Time Switch V
Sys Wind 10 I

Section 2. Operating Features

2.1 Monitor Features

Feature	Benefit
1. Fully automatic patient selection and monitoring	Senses cuff size and automatically switches from Adult/Pediatric monitoring to Neonatal monitoring or vice-versa. Can be programmed to automatically make determinations at various intervals between 1 and 90 minutes.
2. Noninvasive and objective	Helps eliminate risks associated with invasive monitoring and subjective interpretation of auscultatory methods.
3. Oscillometric	No microphones or external transducers are required.
4. Artifact rejection	By observing pulsations of matched amplitude and frequency, the monitor is capable of eliminating most noise and motion artifact (auto and manual modes).
5. Systolic search	Tracks rapid pressure changes.
6. Audible/visual alarm system	Provides a visual and audible indication if systolic, MAP, or pulse rate fall outside of operator programmable high/low limits, and of abnormal system conditions or hardware failure.
7. Microprocessor based design	System fully upgradable.
8. Automatic pressure zeroing	Microcomputer will automatically establish the zero pressure reference before each determination, thus reducing the need for constant calibration verification.
9. Stat mode	Provides an accelerated series of determinations with intermediate systolic update over a five minute period to effectively manage critical situations.
10. Digital displays	Large, easy-to-read displays provide continuous readout of patient parameter values.
11. Two units of measurement*	Can be set to display values in millimeters of mercury (mmHg) or in kilopascals (kPa)*. (Reference Service Manual).
12. Printer Interface	Rear panel output for connection of a Critikon Model 1900 or 1950 Trend Recorder/Printer providing hard copy record of measured parameters and graphic representation of patient trends.
13. Real time clock	Provides (24 hour format) time of determination indication when the monitor is used in conjunction with a Critikon Trend Recorder/Printer. Time of day may be displayed on front panel.
14. Digital-to-analog converter outputs	Rear panel outputs for connection to strip chart recorders. (Reference Service Manual).
15. RS-232 interface	Industry standard interface for compatibility with most computer systems. (Reference Service Manual).

*1 mmHg (or Torr) = 0.133 kPa

Section 3. Indications and Contraindications

3.1 General

The DINAMAP™ Vital Signs Monitor, Model 1846, is intended for use in the non-invasive monitoring of blood pressure and pulse rate. The device is not designed, sold, or intended for use except as indicated.

CAUTION

Federal law restricts this device to sale by or on the order of a physician.

3.2 Limitations

1) Monitor accuracy is dependent on the application of the proper size cuff. It is essential that limb circumference be measured and the proper size cuff be selected as described in Section 6.

2) The monitor will not operate effectively on patients who are experiencing convulsions or tremors.

3) The monitor should not be used on patients who are linked to heart/lung machines.

4) If the cuff is not at heart level, the difference in the reading due to the hydrostatic effect should be noted. The value of 1.80 mmHg must be added to the displayed readings for every inch above heart level. The value of 1.80 mmHg must be subtracted from the displayed readings for every inch below heart level.

5) A patient's vital signs may vary dramatically during the application of agents intended to change the cardiovascular status such as those used to raise or lower blood pressure or raise or lower heart rate.

6) The pulse rate displayed by the monitor may differ from the heart rate displayed by an ECG monitor because the DINAMAP™ Vital Signs Monitor measures actual peripheral pulses, not electrical signals or contractions from the heart. Occasionally, electrical signals at the heart do not produce a peripheral pulse.

7) If a patient is encountering arrhythmias, this will increase the monitor's determination time and may even extend the determination time to beyond the monitor's capabilities (150 seconds).

8) The monitor displays results of the last determination until another determination is completed. If a patient's condition changes during the time interval between determinations, the monitor will not detect the change or indicate an alarm condition.

Section 4. Functional Description

The DINAMAP™ Vital Signs Monitor is a microprocessor controlled, non-invasive device which automatically measures systolic pressure, diastolic pressure, mean arterial pressure, and pulse rate for neonates, children or adults using the oscillometric technique. Results are displayed on four large, easy-to-read digital displays. Determination frequency can be selected by the operator in varied increments between one and ninety minutes. Three operating modes are also selectable (auto, manual, and stat) to cover a variety of clinical situations.

Alarms are provided to alert the operator should systolic, mean arterial pressures or pulse values exceed pre-set* default or operator programmed high/low limits. The monitor provides external output for the connection of a Trend Recorder/Printer which will keep a hard copy record of each determination and graphic representation of patient trends.

*Pre-set internal alarm limits are limits generally found useful in normal clinical situations. They should not be considered as safe limits for any particular patient.

4.1 Determination Sequence (See Figure 4-1)
A determination sequence begins when the START switch (or optional footswitch) is depressed in either manual or auto modes, or when the cycle time has expired in the auto mode. The first determination sequence initially pumps up to a cuff pressure of 178 mmHg for Adult/Pediatric patients, or 120 mmHg for Neonates.

After initial pump-up pressure is reached, the monitor begins a stepped deflation sequence that first determines systole, then MAP (mean arterial pressure), then diastole and pulse rate from pulses induced in the cuff at the varied pressure levels. This is the oscillometric method of determination and is accomplished by a sensitive transducer which not only measures cuff pressure, but also minute pressure oscillations within the cuff.

The monitor deflates the cuff one step each time it detects two pulsations of relatively equal amplitude. Time between deflation steps is dependent on the frequency of these matched pulses (pulse rate of patient), however, if the monitor is unable to find any pulse within 1.6 seconds, it will deflate to the next step. The process of finding two matched pulses at each step provides artifact rejection due to patient movement and greatly enhances the accuracy of the monitor.

At each step the microprocessor stores cuff pressure, the matched pulse amplitude, and the time between successive pulses. The stepped deflation and matched pulse detection continues until diastolic pressure is determined or when total cuff pressure falls below 7 mmHg. The monitor then deflates the cuff (to zero detected pressure), analyzes the stored data, updates the front panel displays and prints the time (24 hour format) and determination results on a Trend Recorder/Printer if attached.

4.2 General Operating Parameters

4.2.1 Maximum-Minimum Ranges
The maximum systolic pressure detected by the monitor is 245 mmHg for Adult/Pediatric patients, and 190 mmHg for Neonates. The minimum detectable systolic pressure is 30 mmHg for all patients.

The maximum MAP (mean arterial pressure) detected is 225 mmHg for Adult/Pediatrics and 170 mmHg for Neonates. Minimum detectable MAP is 20 mmHg for all patients.

The maximum diastolic pressure detected is 210 mmHg for Adult/Pediatrics and 160 mmHg for Neonates. Minimum detectable diastolic pressure is 10 mmHg for all patients.

The maximum pulse rate detected by the monitor is 200 bpm (beats per minute) for Adult/Pediatrics, 220 bpm for Neonates, and the minimum detected is 40 bpm for all patients.

4.3 Basic Operating Cycle
The Operating cycle is comprised of four parts:

- Inflation time
- Deflation time
- Evaluation time
- Wait time

Inflation time, deflation time, and evaluation time comprise the determination sequence and are the same for all modes of operation (auto manual, and stat). Wait time however, will vary from mode to mode and is explained in more detail below.

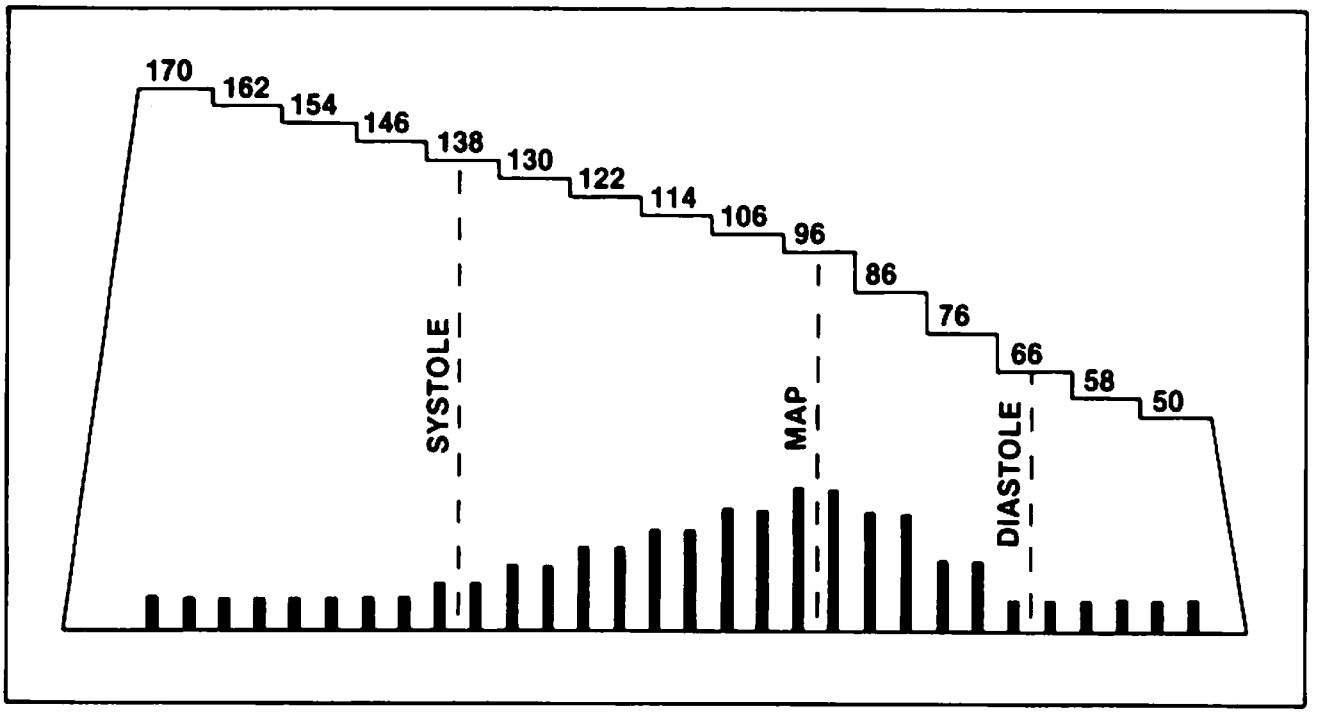

Figure 4-1 Determination Sequence

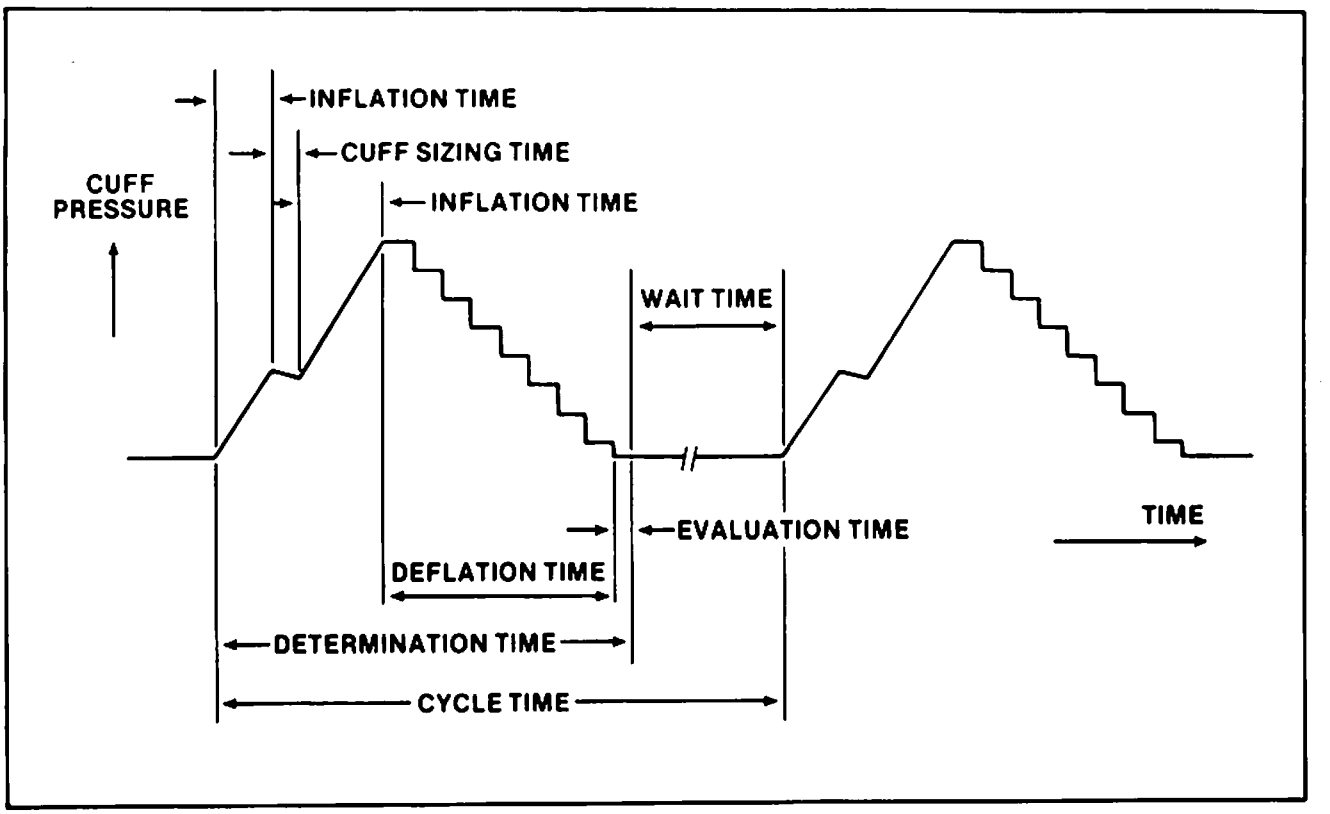

Figure 4-2 Timing Diagram

4.4 Operating Modes

4.4.1 Manual Mode

The manual mode is the normal power-up mode of operation for the monitor (the mode entered automatically after pressing the POWER ON switch). Pre-set default alarm limits automatically activate at power-up but may be changed by the operator to suit any particular patient (see Set Alarms Procedure Section 8.2). In the manual mode, a single determination is made each time (and only when) the START switch is pressed. If a patient alarm is detected a second determination is intiated to verify the alarm. Wait time is indefinite until the START switch is pressed again. Elapsed time (since the last determination) flashes in the CYCLE MINUTES display up to 90 minutes at which time all displays zero and the monitor begins another 90 minute count. Pump-up pressure is based on the results of the last determination.

A determination may be cancelled at any time by pressing the CANCEL switch. This operation will zero the displays, deflate the cuff, place the monitor back into the wait cycle and leave any operator-set alarm limits unaltered. Alarm indicators can be cancelled (after a determination has caused an alarm condition) by pressing the CANCEL switch. This operation will silence and extinguish all patient alarm indicators leaving operator-set alarm limits unaltered.

NOTE

Any momentary power interruption (blackout, brownout, or cycling of the POWER ON/OFF switch etc.) will cause the monitor to revert to manual mode with the pre-set default alarm limits in effect regardless of the operation mode prior to interruption.

4.4.2 Auto Mode

The auto mode may be entered by pressing the AUTO/MANUAL switch. In the auto mode the first determination will be initiated at the expiration of the time set in the CYCLE MINUTES display (or at any time when the START switch is pressed). If a patient alarm is detected, a second determination is initiated to verify the alarm. Subsequent determinations will occur at the expiration of time displayed in the CYCLE MINUTES display. Pump-up pressure is based on the results of the last determination. The CYCLE MINUTES display will periodically show or "flash" the elapsed time since the last determination, then return to the operator set cycle time.

A determination may be cancelled at any time by pressing the CANCEL switch. This operation will zero the displays, deflate the cuff, and begin a new wait time (as displayed in the CYCLE MINUTES display). Any operator set alarm limits will be unaltered. Alarm indicators can be cancelled (after a determination has caused an alarm condition) by pressing the CANCEL switch. This operation will silence and extinguish all patient alarm indicators, begin a new wait period (as displayed in the CYCLE MINUTES display), and leave any operator programmed alarm limits unaltered.

4.4.3 Stat Mode

The stat mode may be entered at any time by pressing the STAT MODE switch. In the stat mode, the monitor will initiate a series of determinations for a five minute period. A determination begun before expiration of the five minute period (at 4 minutes, 55 seconds for example) will cycle to conclusion and results will be displayed before the monitor reverts to the previous mode (manual or auto).

The series begins with cuff inflation to a pressure above previous systolic value, or if no previous systolic is stored, to 178 mmHg for Adult/Pediatrics and 120 mmHg for Neonates. Artifact rejection is relaxed in the stat mode to allow for accelerated determinations. In the stat mode, as the monitor begins stepdown, systolic pressure is displayed the instant that it is determined (usually a few seconds after stepdown begins). The monitor will sound a short tone and "flash" the value in the SYSTOLIC pressure display window to indicate that this is updated information. When MAP, pulse, and diastolic pressure values are determined, the monitor sounds a short tone and these updated values will appear in the respective display windows. The systolic value will be updated and cease to "flash." The monitor will then begin another determination unless the 5 minute period has expired or the operator has pressed the CANCEL switch. Patient alarm limits cannot be accessed during stat mode, however, the occurrence of an out-of-limits alarm will be noted on a Trend Recorder/Printer (if attached) and will not inhibit the series of determinations or display of values. At the expiration of the 5 minute stat mode period or after pressing the CANCEL switch, the monitor will automatically revert to the mode of operation prior to initiation of the stat mode (manual or auto).

4.4.4 Neonatal or Adult/Pediatric Monitoring

These are switched automatically. The monitor contains two sets of standards: One for Adult/Pediatric patients and the other for Neonatal patients. Pre-set default alarm limits as well as pump-up pressure and internal algorithms are altered in the Neonatal mode.

The monitor will automatically switch into the proper mode by sensing cuff size and requires no operator intervention.

4.4.5 Systolic Search
In any operating mode, should a patient's systolic pressure exceed the monitor's pump-up pressure, the unit will:

1. Begin normal deflation sequence
2. Detect the absence of a systolic value
3. Stop deflation
4. Re-inflate to a higher (than initial) pump-up pressure
5. Resume normal deflation sequence

The monitor will continue to use this higher pump-up pressure through subsequent determinations until such time as the patient's systolic pressure falls. The unit will then lower pump-up pressure accordingly.

4.5 Undetermined Systolic and Diastolic Pressures
Under certain circumstances, the monitor may display only MAP and not display values for systolic and diastolic pressures. If the patient is in shock, the systolic/diastolic waveform has very low amplitude fluctuations as shown below.

Because of the relatively small difference between systolic and diastolic pressure in a shock situation, only MAP can be accurately determined and displayed.

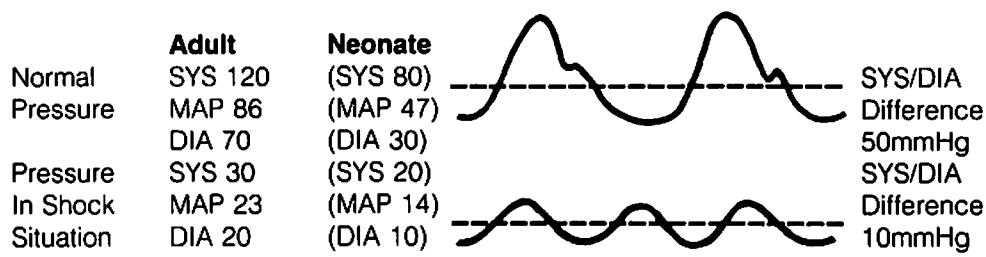

Figure 4-3 Low Amplitude Waveform Diagram

Section 5. Physical Description

5.1 Operating Requirements
Section 5 contains a physical description of the monitor's controls, indicators, and connectors. Covered in Table 5-1 are general, physical characteristics and operating requirements. For the complete list of technical specifications refer to Sections 13 through 16.

5.1.1 Physical Characteristics/Operating Requirements

MONITOR DIMENSIONS	
Height	4.75 inches
Width	10.75 inches
Depth	10.75 inches
WEIGHT	18 lbs. max (60 Hz Unit) 19 lbs. max (50 Hz Unit)
POWER REQUIREMENTS	
Input Power	0.8 Amps max.@100, 120 VAC 0.5 Amps max.@220, 240 VAC
Input Voltage (Domestic)	120 VAC/60 Hz (nom.), 104-132 VAC/ 57-63 Hz
(International)	100 VAC/50 Hz (nom.), 88-112 VAC/ 47-63 Hz 220 VAC/50 Hz (nom.), 194-246 VAC/ 47-63 Hz 240 VAC/50 Hz (nom.), 212-268 VAC/ 47-63 Hz
FUSE REQUIREMENTS	120 VAC/60 Hz-1 each, 1 1/2A, 3AG, SLO-BLO @ 120 V. 100 VAC/50 Hz-1 each, 1 1/2A, 3AG, SLO-BLO @ 120 V. 220 VAC/50 Hz-2 each, 0.8A, FST, SLO-BLO @ 250 V. 240 VAC/50 Hz-2 each, 0.8A, FST, SLO-BLO @ 250 V.
PRINTER FUSES	100/120 VAC, 3A SLO-BLO @ 250V 220/240 VAC, 3.15A SLO-BLO @ 250V
OPERATING TEMPERATURE	+50°F to +104°F (+10°C - +40°C)
STORAGE TEMPERATURE	−29°F to +167°F (−34°C - +75°C)
HUMIDITY RANGE	0 to 95% non-condensing
ALTITUDE RANGE	−1000 to +15,000 feet

Table 5−1 General Characteristics/Operating Requirements

5.2 Controls and Indicators Controls and indicators are situated on both the front and rear panels of the DINAMAP™ Vital Signs Monitor. The front panel controls and indicators are shown in figure 5-1 and defined in Table 5-2. The rear panel controls and indicators are shown in Figure 5-2 and defined in Table 5-3.

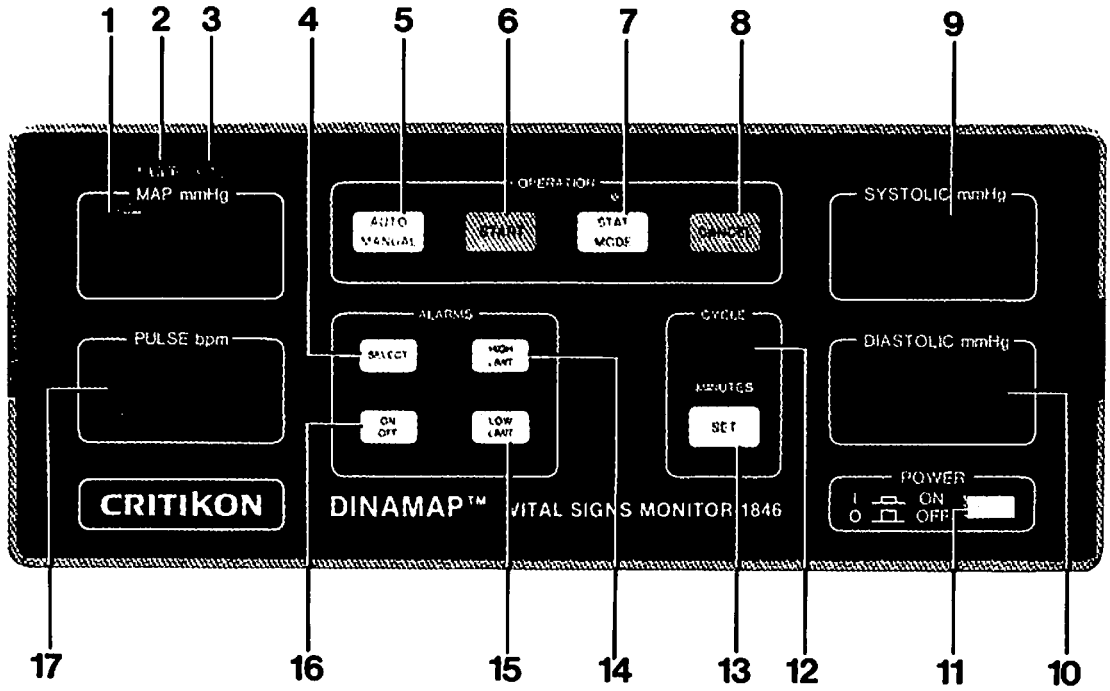

Figure 5-1 Front Panel Controls and Indicators

Table 5-2 Front Panel Controls and Indicators Defined

Reference	Placard	Function
1	MAP mmHg	This 3-digit red LED display shows mean arterial pressure. In addition this display: • Flashes cuff pressure during deflation time • Shows hours contained in the 24 hour clock when TIME OF DAY is depressed • Displays MAP alarm limits (see reference 4, SELECT).
2	CUFF	This illuminated indicator signifies that a determination is in progress.
3	kPa	kPa indicators will only light if internal kPa switch is set.
4	SELECT	This momentary pushbutton switch selects the alarm limits to be displayed. Pressing the switch the first time will blank all displays, except SYSTOLIC, and allow the HIGH LIMIT and LOW LIMIT switches to be used to display the high and low systolic alarm limits in the SYSTOLIC display. Pressing the switch a second time will blank all displays, except MAP, and allow the HIGH LIMIT and LOW LIMIT switches to be used to display the high and low MAP alarm limits in the MAP display. Pressing the switch a third time will allow setting pulse rate high and low limits in the same manner. Pressing the switch a fourth time will return the values of the last determination to all displays. There is a 10 second time limit for each of these operations, at which time the monitor automatically returns to the previous displays.

Table 5-2 Front Panel Controls and Indicators Defined (Cont'd)

5	AUTO/MANUAL	This momentary pushbutton switch with adjacent LED indicators controls and indicates the mode of operation for the monitor. Pressing this switch will change the operating mode as indicated by the associated green LED. Manual mode is entered when power is first applied to the monitor. A single determination is made each time the START switch (or footswitch) is pressed. In auto mode, determinations are initiated at the end of the cycle time shown in the CYCLE MINUTES display (reference 12). Determinations may also be initiated by pressing the START switch (or footswitch) during wait time. The cycle timer is started when auto mode is first entered and is restarted at the beginning of each automatic determination.
6	START	This momentary pushbutton switch will initiate a determination in manual or auto mode. The START switch will initiate a determination only during wait time; if pressed during any other time, there will be no effect. In manual mode, determinations are initiated only by pressing the START switch. In auto mode, pressing the START switch will initiate a determination, zero the elapsed time, and begin a new cycle.
7	STAT MODE	This momentary pushbutton switch and yellow LED selects and indicates the stat mode of operation. Stat mode may be entered at any time from manual or auto mode and will perform continuous determinations for a 5 minute period. Patient alarms cannot be accessed during STAT mode, however, the occurrence of an out-of-limits alarm will be noted on a Trend Recorder/ Printer (if attached) and will not inhibit the series of determinations or display of values. At the end of the 5 minute period, the monitor will return to the mode it was in before stat mode was initiated. If that mode was auto, cycle time will begin at the end of the last determination in stat mode. If that mode was manual, the monitor will return to the wait time state. Exit from the stat mode may be accomplished at anytime by pressing CANCEL. This will return the monitor to the mode it was in before stat was initiated. If that mode was auto, the cycle time will begin when CANCEL is pressed.
8	CANCEL	This momentary pushbutton switch performs several functions. Pressing this switch will terminate a determination, cancel all visual and audible alarms except certain system alarms (see Table 10-1), exit stat mode, and exit the calibrate mode. If CANCEL is pressed during inflation time, or if CANCEL is pressed during stepping time, the determination will be aborted and the displays zeroed. Visual and audible alarms may be cancelled during wait time and the displays will maintain the last determined values.
9	SYSTOLIC mmHg	This 3-digit red LED display shows systolic pressure. In addition this display: • Shows minutes contained in the 24 hr. clock when TIME OF DAY is pressed • Displays systolic alarm limits (see reference 4, SELECT).
10	DIASTOLIC mmHg	This 3-digit red LED display shows the diastolic pressure.
11	POWER ON OFF	This pushbutton latching switch controls the AC power to the monitor.

Table 5-2 Front Panel Controls and Indicators Defined (Cont'd)

12	(CYCLE) MINUTES	This 2-digit, red LED display shows the cycle time in minutes when in automatic mode. The display is blanked when in manual or stat modes. When in manual mode, elapsed time (since the last determination) is flashed in the CYCLE MINUTES display. When auto mode is first entered, the display indicates the cycle time of 3 minutes. This may be changed by using the SET switch. The elapsed time of the current cycle is briefly displayed periodically to indicate the amount of time elapsed since the beginning of the last determination. Pressing START at any time will zero the elapsed time and begin a new cycle and new determination. Pressing CANCEL during a determination will zero the elapsed time and begin a new cycle.
13	SET	This momentary pushbutton switch increments the MINUTES when in auto mode. The MINUTES increments are 1, 2, 3, 4, 5, 10, 15, 20, 30, 45, 60 and 90 minutes. Changing MINUTES will zero the elapsed time and begin a new cycle immediately. Pressing SET, as power is applied, will place the unit in calibrate mode (see Section 9). Calibrate mode can be exited by pressing CANCEL. This will zero the displays and return the unit to manual mode.
14	HIGH LIMIT	This momentary pushbutton switch displays the current high alarm limit selected by the SELECT switch. If pushed and held, the switch will cause the display to step through the entire range of high limit settings (settings overlapping the low limit will not be displayed). Whatever setting is displayed at the time the SELECT switch is released will be the new high limit alarm setting.
15	LOW LIMIT	This momentary pushbutton switch displays the current low alarm limit selected by the SELECT switch. If pushed and held, the switch will cause the display to step through the entire range of low limit settings (settings overlapping the high limit will not be displayed). Whatever setting is display at the time the SELECT switch is released, will be the new low limit alarm setting.
16	ALARMS ON/OFF	This momentary pushbutton switch with LED indicators controls the state of the audio alarm. In the ON state, the green (top) LED will be lit and when an alarm condition is detected, the audio alarm will sound and the green LED will flash on and off. In the OFF state, the yellow (bottom) LED will be lit and when an alarm condition is detected, the audio alarm will be inhibited and the yellow LED will flash on and off.
17	PULSE bpm	This 3-digit red LED display shows the last determined pulse rate. In addition this display: • Displays the 800 series alarm codes during certain alarm conditions (refer to Section 11). • Displays pulse rate alarm limits (see reference 4, SELECT).

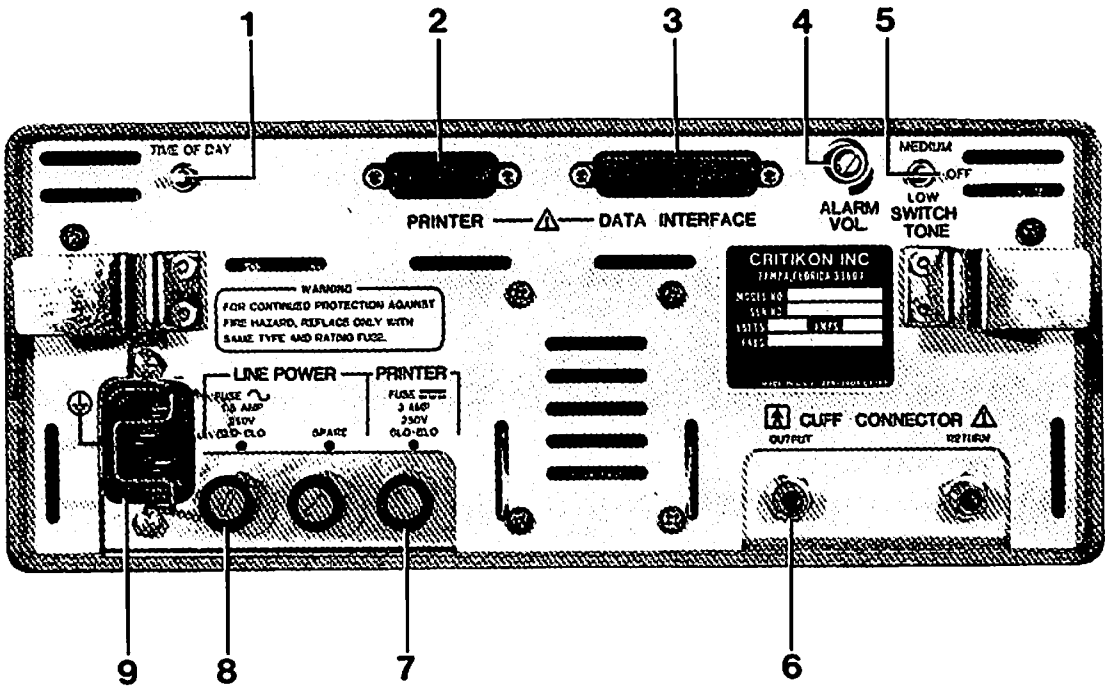

Figure 5-2 Rear Panel Controls and Indicators

Table 5-3 Rear Panel Controls and Indicators Defined

Reference	Placard	Function
1	TIME OF DAY	This 3-position switch displays and sets the time of day. (See Section 8.6 for procedure). Moving this switch to the momentary TIME OF DAY position displays the contents of the 24 hour clock in the MAP and SYSTOLIC displays. Hours are displayed in the MAP display; minutes in the SYSTOLIC display. If the time of day is flashed at a 1 Hertz rate, this indicates that the clock battery on the CPU board is low and in need of replacement.
2	PRINTER	Connector port for connection of Trend Recorder/Printer cable.
3	DATA INTERFACE	Connector port for connection of analog strip chart recorder or external computer.
4	ALARM VOL.	This potentiometer adjusts the volume of the audio alarms (except failsafe). Turning the control clockwise will increase the volume, counterclockwise will decrease the volume. This control cannot silence the audio alarm, it can only attenuate it.
5	SWITCH TONE	This 3-position switch controls the volume of the audible switch tones. When a valid front panel switch entry is made, a single, short audio tone is generated at the rear panel speaker. When an invalid entry is attempted, three lower frequency audio tones are generated. The OFF position eliminates these audio tones.
6	CUFF CONNECTOR	Screw type connectors for connection of pneumatic (cuff) hose.

Table 5-3 Rear Panel Controls and Indicators Defined (Cont'd)

7	PRINTER Fuse	Printer fuse (functional when Model 1950 Trend Recorder/Printer is attached), (See Section 15 for rating).
8	LINE POWER Fuse	Monitor fuse, (See Section 15 for rating).
9	Power Cord Connector	AC power cord connector with retaining clip.

Section 6. Monitor Installation

6.1 Initial Set Up

Section 6 contains preparation and initial set-up instructions, electrical and pneumatic hose connections, as well as cuff size and placement instructions.

6.1.1 Unpacking the Monitor

The monitor's shipping carton should contain the items listed in Table 6-1 below. Account for and inspect each item. If an item is missing call your sales representative, or Critikon, Inc. Customer Service at 1-800-237-7517 (1-800-282-7533 in Florida). If the instrument is damaged, contact Field Service at 1-800-237-5591 (1-800-282-9151 in Florida). Fill out and mail the Warranty Registration Card found in this manual.

Note

It is advisable to keep the original materials (box,inserts) in which your monitor was shipped in the event that you wish to store the unit or return it to a Service Center for repair.

Monitor Checklist

1 - Vital Signs Monitor Model 1846
1 - Operation Manual
1 - Cuff (Standard Adult)
1 - Pneumatic Hose with Connectors (12 ft. - Adult/Pediatric)
1 - Pneumatic Hose with Luer Connector Block (8 ft. - Neonatal)
1 - Set Neonatal Cuffs (4 per set)
1 - Calibration Kit
1 - Power Cord
X - Optional Accessories as Ordered

Table 6-1

6.1.2 Electrical and Hose Connections

With Monitor Off:

1. Check the voltage rating stamped on the serial number plate attached to the rear of the monitor and make sure it matches the line voltage of the receptacle to be used.
2. Connect the detachable 10-foot power cord to the monitor and engage the cord lock on the rear panel. Plug the other end into an appropriate voltage receptacle.
3. Connect the dual-pneumatic hoses to the monitor at the rear panel. There is no preferred order of connection; either hose may be connected to either port. Thread the hose connectors onto the monitor ports until finger-tight. DO NOT OVERTIGHTEN. The pneumatic seal is NOT made by tightening the connector.
4. Measure the limb of the patient and select the proper size cuff according to the size marked on cuff or cuff package.

Cuff Type	Use Hose No.
Neonate #1	330-020
Neonate #2	330-020
Neonate #3	330-020
Neonate #4	330-020
Infant	330-017
Child	330-017
Small Adult	330-017
Adult	330-017
Large Adult	330-017
Thigh	330-017

Table 6-2 Cuff-to-Hose Compatibility

5. Connect the cuff to the hoses. Thread the cuff connectors onto the hose connectors. DO NOT OVERTIGHTEN.
6. Squeeze all the air from the cuff.
7. Place the cuff on the patient as shown in Figure 6-1. Observe the mark on the inside of the cuff to be placed over the artery. Be sure the cuff is not so tight as to prevent venous return between determinations.

NOTE

EXCESSIVE TIGHTNESS WILL CAUSE CONGESTION AND DISCOLORATION OF THE LIMB.

Note: Do not place the cuff on an extremity being used for intravenous infusion.

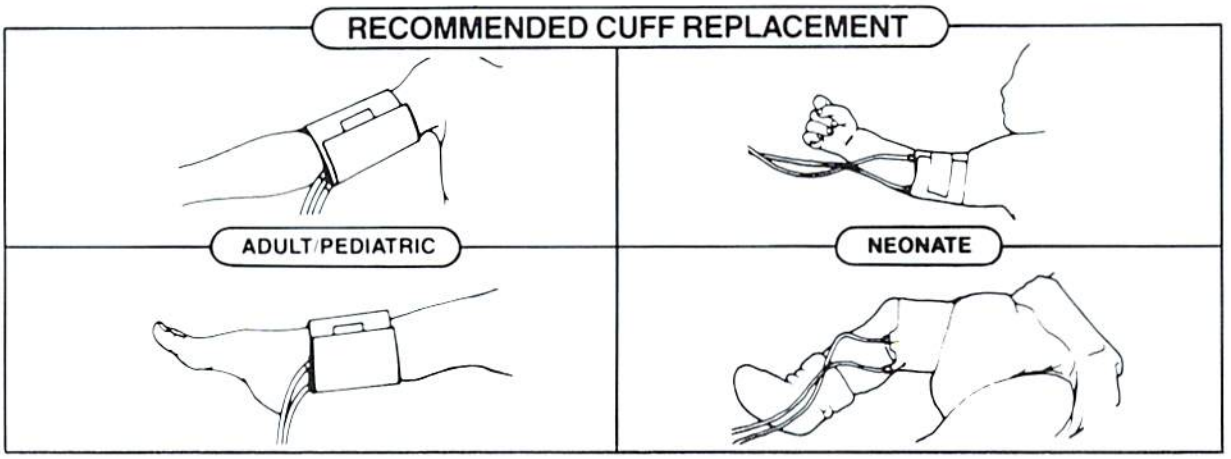

Figure 6-1 Cuff Placement

8. If it becomes necessary to change the cuff to another limb, make sure the appropriate size cuff is used.

NOTE

To obtain accurate determinations, extremity and cuff motion must be minimized.

9. Before powering up the monitor, read/review all operating precautions listed in Section 7.

Section 7. Operating Precautions

7.1 Operating Precautions

Although the DINAMAP™ Vital Signs Monitor has been designed to provide safe and reliable operation in medical environments, a responsible operator will observe the following precautions to ensure the safe and reliable operation of this unit.

1) Read and have a thorough understanding of the material presented in this manual.

2) Read and observe all the caution and warning labels affixed to the unit.

3) Place the monitor on a rigid, secure surface.

4) Arrange the power cord and pneumatic hoses carefully so they do not constitute a hazard.

5) Allow for heat dissipation by ensuring that the rear of the chassis is unobstructed.

6) Do not place fluids on the monitor.

7) Do not use the monitor in the presence of flammable anesthetics.

8) A momentary power interruption will cause the monitor to revert to manual mode with preset default alarm limits in effect.

Section 8. Operating the Monitor

8.1 Power-up Procedure

1. Push in the locking POWER ON switch and observe that the monitor momentarily displays eights in all digital displays and flashes all indicators as a check for the operation of all LEDs. The audio alarm is also warbled as a check for its operation.

2. Set the ALARM VOL. control on the rear of the monitor to the desired level by turning the monitor off and on while adjusting the control.

3. Set the SWITCH TONE switch on the rear of the monitor to the desired position.

4. Set the audio ALARM ON/OFF switch on the front panel to the desired mode. In ALARM ON, the monitor will generate an audio alarm for any alarm condition and the green LED indicator will flash. In ALARM OFF, the audio alarm is inhibited for all patient and excess time alarm conditions and the yellow LED indicator will flash. Any 800, 811, 822, 866, or 877 alarm cannot be audio disabled (See Table 10-1).

5. Check and/or set the time of day using the TIME OF DAY switch on the rear of the unit.

6. Set the systolic, MAP and pulse alarm limits if it is desired that these limits be changed from the preset values.

8.2 Set Alarm Limits Procedure

The preset default alarm limits are in effect each time power is first applied to the monitor. These limits are as follows:

	Adult	**Neonate**
SYSTOLIC high limit =	240 mmHg	240 mmHg
SYSTOLIC low limit =	0 mmHg	0 mmHg
MAP high limit =	140 mmHg	100 mmHg
MAP low limit =	50 mmHg	30 mmHg
PULSE high limit =	220 bpm	220 BPM
PULSE low limt =	40 bpm	40 BPM

Table 8-1 Preset Default Alarm Limits

If it is desired to change these limits, perform the following steps:

1. Momentarily press SELECT to enable the SYSTOLIC display to show the systolic alarm limits. All other displays will be blanked and the SYSTOLIC display will show zero (or the systolic value of the previous determination).

2. Momentarily press HIGH LIMIT to display the current systolic high limit. Press and hold HIGH LIMIT to cause the monitor to increment through the high alarm range settings. Release the HIGH LIMIT switch at the desired setting.

3. Momentarily press the LOW LIMIT switch to display the current low limit in the SYSTOLIC display. Press and hold LOW LIMIT to cause the monitor to increment through the low alarm range settings. Release the LOW LIMIT switch at desired setting.

4. Momentarily press the SELECT switch to enable the MAP display to show the MAP alarm limits. All other displays will be blanked and the MAP display will show zero (or the MAP of the previous determination if one was performed).

5. Momentarily press HIGH LIMIT to display the current high limit in the MAP display. Press and hold HIGH LIMIT to cause the monitor to increment through the high alarm range settings. Release the HIGH LIMIT switch at the desired setting.

6. Momentarily press the LOW LIMIT switch to display the current low limit in the MAP display. Press and hold the LOW LIMIT switch to cause the monitor to increment through the low alarm range settings. Release the LOW LIMIT switch at the desired setting.

7. Momentarily press the SELECT switch to enable the PULSE display to show the pulse alarm limits. All other displays will be blanked and the pulse display will show zero (or the pulse of the previous determination if one was performed).

8. Momentarily press HIGH LIMIT to display the current high limit in the PULSE display. Press and hold HIGH LIMIT to cause the monitor to increment through the high alarm range settings. Release the HIGH LIMIT switch at the desired setting.

9. Momentarily press the LOW LIMIT switch to display the current low limit in the PULSE display. Press and hold the LOW LIMIT switch to cause the monitor to increment through the low alarm range settings. Release the LOW LIMIT switch at the desired setting.

10. Momentarily press the SELECT or CANCEL switch to return the display to normal operation. If no switch is pressed within a 10 second period while setting limits, the monitor will automatically return to the normal display.

8.3 Manual Mode

1. Press START to begin each determination.

2. Press CANCEL to abort a determination and deflate cuff, or to cancel excess time and patient alarm indicators.

8.4 Auto Mode

1. Press AUTO/MANUAL to enter auto mode. Auto mode is indicated by the LED above the AUTO/MANUAL switch and the appearance of the cycle time in the CYCLE MINUTES display.

2. Preset cycle time is 3 minutes. To change the cycle time, press and hold the CYCLE SET switch until the desired cycle time appears in the display then release the switch. The display will briefly show the amount of time which has expired since the last determination was initiated. A determination may be initiated manually at any time during the wait period by pressing the START switch. This will zero the elapsed time and begin a new wait cycle.

3. Press CANCEL to abort a determination and deflate cuff, or to cancel excess time and patient alarm indicators.

8.5 Stat Mode

1. Press STAT MODE to start a 5 minute period of continual determinations. After each determination, the cuff is deflated to allow for venous return. Patient alarms cannot be accessed during STAT mode, however, the occurence of an out-of-limits alarm will be noted on a Trend Recorder/Printer (if attached) and will not inhibit the series of determinations or display of values. Stat mode may be entered from manual or auto mode during wait time. During stat mode, if the systolic, MAP or pulse rate alarm limits are exceeded, the alarms will not be generated but will be noted on a Trend Recorder/Printer (if attached) and the determinations will continue until the 5 minute period is completed.

2. After 5 minutes, or whenever the CANCEL switch is pressed, the monitor will return to the previous operating mode. If the previous mode was auto, the elasped time will be zeroed and a new cycle will be started.

8.6 Setting Time of Day

1. Momentarily push up the TIME OF DAY switch on the rear panel to display the hours (MAP display) and the minutes (SYSTOLIC display) of the 24 hour clock.

2. Push up and hold the TIME OF DAY switch until SYSTOLIC and MAP displays zero. Release the switch and observe that hours (tens) digit cycles between 1 and 2.

3. When the correct digit is displayed, momentarily push the TIME OF DAY switch up and observe that the hours (tens) digit is fixed and that the hours (units) digit begins incrementing from 0 to 9.

4. When the correct digit is displayed, momentarily push the TIME OF DAY switch up and observe that the hours (units) digit is fixed and that the minutes (tens) digit begins incrementing from 0 to 5.

5. When the correct digit is displayed, momentarily push the TIME OF DAY switch up and observe that the minutes (tens) digit is fixed and that the minutes (units) digit begins incrementing from 0 to 9.

6. When the correct digit is displayed, momentarily push the TIME OF DAY switch up and observe that the minutes (units) digit is fixed and the monitor reverts to the normal operating mode. Once set, the time of day clock will continue to run (even with power off or the monitor unplugged) for the duration of the battery life. Battery life is rated at 2 years minimum. When the battery is low, the time of day will flash when displayed in the MAP and SYSTOLIC displays. The battery must be changed by a qualified service representative.

Section 9. Periodic Maintenance

9.1 Performing Calibration Check

Calibration of the monitor should be checked at least once a month or when there is doubt about the validity of the pressure readings. To perform a calibration check, follow these procedural steps:

1. Obtain the calibration kit (Reorder number 8886) supplied with the unit.

2. Connect a mercury manometer to the monitor using the parts supplied with the calibration kit as shown in Figure 9-1.

3. Plug the monitor into the specified line power outlet.

4. Press and hold the SET switch while pressing the POWER ON switch. Flashing 88's in CYCLE MINUTES display confirms that calibration mode has been entered. The unit will turn on, light the CUFF indicator, and display cuff pressure in the MAP display.

5. Using the inflation bulb, manually pump up the pressure to 200 mmHg, ±1 mmHg, as indicated by the mercury manometer and close pneumatic release valve on manometer bulb.

6. Verify that the pressure indicated by the mercury manometer does not decrease more than 12mmHg in 60 seconds for all cuff and hose combinations. If the leak down is greater than 12mmHg in 60 seconds, check cuff and hose junctions and rubber "O" rings for cracks, tears, or breaks. If no cuff or hose leaks are found, refer to qualified service personnel.

7. Verify that the MAP display indicates the correct pressure at the following pressure levels:

Manometer Indicated Pressure Level	MAP Display
200 mmHg, ±1mmHg	200 mmHg, ±5mmHg
150 mmHg, ±1mmHg	150 mmHg, ±4mmHg
100 mmHg, ±1mmHg	100 mmHg, ±4mmHg
50 mmHg, ±1mmHg	50 mmHg, ±4mmHg
0 mmHg	0 mmHg, ±3mmHg

Table 9-1 Calibration Check

8. If the indicated pressures are not within tolerance, the monitor must be calibrated. Refer to qualified service personnel.

9. Pump up manometer using the manometer bulb and verify at a pressure between 265 mmHg and 285 mmHg the monitor briefly blanks the displays, then opens the deflate valves and issues an 800 alarm.

10. If the overpressure point is not within tolerance (~~275~~ mmHg ± 10 mmHg), the overpressure switch must be adjusted. Refer to qualified service personnel. 3 VALUES 350 ± 10
2 VALUE 300 ± 15

9.2 Cleaning

The exterior of the monitor may be wiped clean with a cloth slightly dampened with mild detergents. DO NOT immerse unit. DO NOT clean with isopropyl alcohol or other solvents.

9.3 Storage

If it becomes necessary to store the monitor for an extended period of time, attach the original packing inserts, and place the unit into the original shipping carton. See Section 14 for storage temperature information.

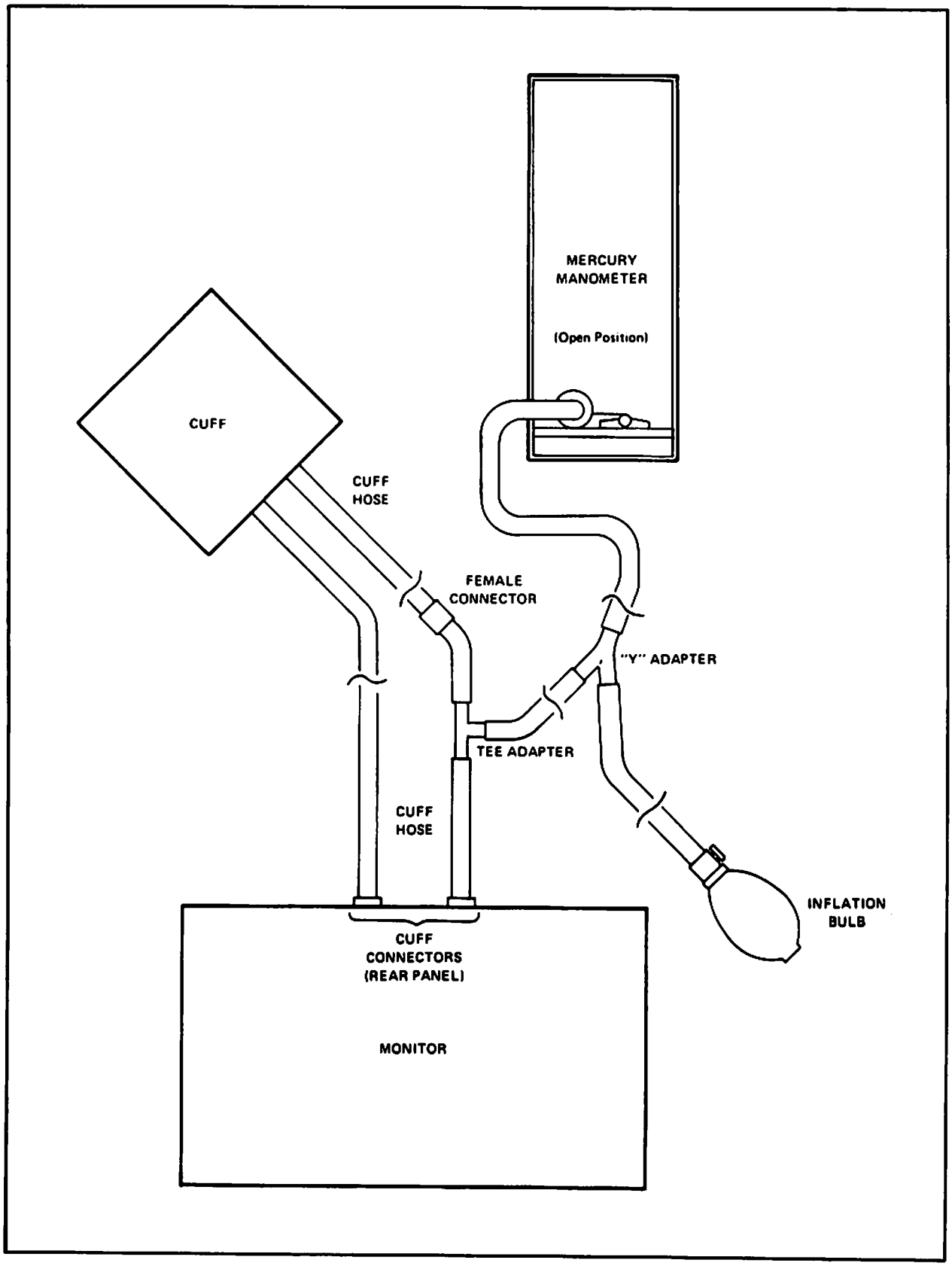

Figure 9-1 Calibration Check Set-up

Section 10. Alarm Indications and Interpretation

All alarm indications are accompanied by an audio signal unless the ALARM ON/OFF switch is in the OFF state. In the ALARM OFF state, an alarm condition (other than a microprocessor system failure) is indicated by a flashing ALARM OFF indicator (yellow LED). In the ALARM ON state, the alarm audio level may be adjusted by the AUDIO VOL. control for all alarms except a microprocessor system failure.

A microprocessor system failure will generate a continuous, high level audio alarm regardless of the setting of the ALARM ON/OFF switch or the AUDIO VOL. control.

There are two categories of alarms: Patient alarms and system alarms.

10.1 Patient Alarms

Patient alarms include those alarms issued when the patient's systolic pressure, mean arterial pressure, or pulse rate is outside the set limits. Whenever one of these conditions occurs, the associated display (SYSTOLIC, MAP, or PULSE) will flash the determined value and a continuous high/low frequency audio alarm will be issued. If a Trend Recorder/Printer is attached to the monitor, the printed numeric value of the parameter in the alarm condition is preceded with an asterisk to show that the limit for that value has been exceeded.

Pressing the ALARM ON/OFF switch to OFF will silence the audio alarm, but the alarming parameter display and ALARM OFF indicator will continue to flash at the same rate.

Pressing the CANCEL switch will cancel all alarm indications.

Whenever the monitor detects a patient alarm condition, whether in manual or auto mode, the monitor will activate the alarms and immediately begin one more determination (unless CANCEL is pressed) to ascertain the alarm condition. If the alarm condition persists, no further determinations are made.

10.2 System Alarms

There are twelve system level alarms to alert the operator to certain abnormal conditions or internal system failures. Alarm conditions and remedies are discussed in Section 11, however, Table 10-1 is also provided for quick reference.